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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,851	09/09/2003	Christopher J. Murphy	TPLANT-08360	2123
21091	7590	03/09/2006	EXAMINER	
JOHN H CROZIER 1934 HUNTINGTON TURNPIKE TRUMBULL, CT 06611			LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/657,851

Applicant(s)

MURPHY ET AL.

Examiner

Samuel W. Liu

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-67 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of claims

Claims 53-67 are pending.

The preliminary amendment filed 9/9/03, which cancels claims 1-52 and add claims 53-67, has been entered. Pending claims 53-67 are examined in this Office action.

Objection to Specification

The disclosure is objected to because of the following informalities:

(1) The continuing data of the current application is needed to be updated.

(2) On page 2, line 7, "HTK" should be spelled out for the first instance of use; see also page 4, line 21, "IGF-1" "EGF" and "NGF".

(3) The current the specification does not comply with one or more parts of 37 CFR 1.821-1.825 since on page 19, lines 15-16, the specification recites amino acid sequences "KLAKKLA", "KLAKLAK", "KALKALK", "KLGKKLG" and "KAAKKAA" without the requisite "SEQ ID NOs." for the indicated amino acid sequences. Correction is required. A new paper copy and a computer readable form (CRF) are required as is the statement regarding no new matter and that the paper and CRF copies are identical.

(4) In claim 55, "about 1 to 200 g/l" should be changed to "about 1 g/l to 200 g/l" in order for consistency (see claim 53 recitation "*about 1 ng/ml to 100 ng/ml*"). Similarly, see claim 59 ("about 0.01 to 1000 mg/l"), claim 60 ("about 1 to 500 mM"), claim 66 ("about 1 to 500 mM"), and claim 67 ("about 1 to 200 g/l").

Appropriate correction is required.

Objection to Drawing

Figure 9 is objected to because the figure should be presented in a transparent background.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 58 is indefinite because SEQ ID NO:37 is a polypeptide sequence which has no ability of encoding the defensin polypeptide.

Claim Rejection -Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1653

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 53 and 56-62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10, 12 and 14-17 of U.S. Patent No. 6696238. Although the conflicting claims are not identical, they are not patentable distinct from each other because of the following reasons. .

Claims 10 and 16-17 of 6696238 disclose a composition comprising lactobionate and insulin-like growth factor 1 (IGF-1). And, on column 29, line 8 and Tables 11-17 (columns 31-32), 6696238 teach that IGF-1 concentration is about 10 ng/ml. Thus, claims 10 and 16-17 of 6696238 are obvious variation of instant claim 53.

Claim 10 of 6696238 discloses that the composition comprises an antimicrobial peptide, defensin, which is the common subject matter to instant claims 56-57.

Claim 15 of 6696238 teaches that defensin has the amino acid sequence of SEQ ID NO:37 which is identical to instant SEQ ID NO:37, which is an obvious variation of instant claim 58.

Claim 12 of 6696238 teaches that defensin is present in a concentration of about 0.01 mg/l to 100 mg/l, which is the common subject matter to instant claims 59.

Art Unit: 1653

Claim 13 of 6696238 teaches that lactobionate is present in a concentration of about 1 mM to 500 mM, which is the common subject matter to instant claims 60.

Claim 17 of 6696238 teaches that the composition further can comprises substance P; and on Tables 11-17 (columns 31-32), 6696238 teaches that the concentration of said substance P is about 10 µg; and thus, claim 17 is an obvious variation of instant claims 61-62.

Conclusion

No claims are allowed.

The following art made of record and not currently relied upon in any rejections is considered pertinent to Applicants' disclosure:

- Hancock et al. (US Pat. No. 6172185 B1) teach a polypeptide of SEQ ID NO:1 which ha 100% sequence identity to the instant SEQ ID NO:37 polypeptide. Yet, Hancock et al. do not teach or suggest a composition comprising lactobionate and insulin-like growth factor 1 (IGF-1).

- Hancock et al. (WO 9960016) teach a polypeptide of SEQ ID NO:1 which ha 100% sequence identity to the instant SEQ ID NO:37 polypeptide. US Pat. No. 6172185 is the other version of this patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

Art Unit: 1653

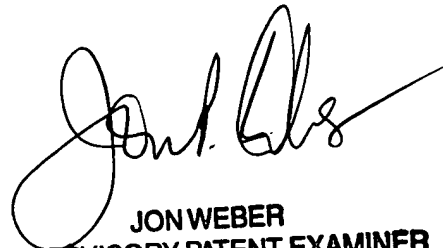
supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



Samuel Wei Liu, Ph.D.

Art Unit 1653, Examiner

February 27, 2006



JON WEBER
SUPERVISORY PATENT EXAMINER